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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,406	08/24/2001	Ben-Zion Dolitzky	1662/49603	5473

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EXAMINER
BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/939,406	Applicant(s) DOLITZKY et al.
	Examiner Emily Bernhardt	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 2/11/02 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-36, 49, and 51-67 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-36, 49, and 51-67 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

In view of applicant's response filed 2/11/02 the following applies.

Parent history in specification as now amended is objected to. Note that the order of applications should be reversed and appear as one sentence. See MPEP 1302.04 for typical formats.

The amendment filed 2/11/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: R1 as H. In making this amendment applicant points to example 2 for support but this one compound is not made directly from the process claimed herein but only after recovery of piperazine product. Additionally having one compound exemplify R1 as H cannot support a genus of varying R variables as claimed herein. See Ex parte Winters 11 USPQ 2nd 1387; Ex parte Westphal 26 USPQ 2d 1858 regarding reliance on a species to create a generic concept.

Applicant is required to cancel the new matter in the reply to this Office action.

Claims 1,2,4-20,22-36,49,51-54,56,57,59-64,66-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1.R^1 as H lacks descriptive support in the disclosure as originally filed. See remarks made directly above regarding this choice as being new matter.

2.The newly added proviso also lacks descriptive support. Its presence creates a new subgeneric concept which is not seen by way of preferred embodiments or working examples to be part of applicant's invention. Note Ex parte Grasselli 231 USPQ 393 regarding the addition of a new limitation, especially on p.394,right column where it is stated: "It might be added that the express exclusion of certain elements implies the permissible **inclusion** (emphasis added) of all other elements not so expressly excluded." .

Claims 1-36,49,51-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.Scope of "aryl" wherever it appears, either alone or as part of a more complex moiety such as arylalkoxy, requires clarification since newly added proviso excluding certain substituents on phenyl implies other (undisclosed) groups can be present yet specification provides no guidance except for exemplifying phenyl as "aryl" .

2. "Amine" is still present in new claim 58. See reason # 2 of the previous action.

Claims 1-36,49,51-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant process and reactants, and products made are disclosed to be solely useful in ultimately making mirtazapine or its derivatives as disclosed in US 4,062,848 which is incorporated by reference on p.2 of the specification. In reviewing the scope of R variables permitted in the instant process and compound claims it is noted the scope entails far more than what is ultimately taught to be within the disclosure of US'828. Compare instant R2 scope with R2 in van der Burg as well as scope of R3 with R1-containing phenyl ring in US'828. Also it is

not seen how R3 other than phenyl (sole moiety described herein) can make the outer phenyl ring present in mirtazapine. Additionally cleavage of **all** R1 variables has not been shown can be achieved employing the hydrolysis condition shown for R1 as tosyl. Note R1 can be alkyl,aryl, arylalkoxy and amino . Acyl-derived groups are known to be hydrolytically cleavable. Also it would appear that the R3 variable done must always be alpha to the N-R1 nitrogen to make mirtazapines via the instant process and yet the R3 group is permitted to float in most of the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 49, 58-63 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Nickolson. The publication discloses a compound within the instant scope in Table 1, no.10.

Claims 49,63,64,66 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafon (US'110). The US patent discloses several compounds within the instant scope. See col.2 after formula (I) as well as Table I.

Claims 1,2,4-10,19,20,22-28 and 49,58-61,63,66 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivie (US'452). US'452 is a CIP of US'

513 which previously anticipated the claims. Applicants' proviso while excluding two choices of X exemplified in Olivie, US'513, appears to include other aryl groups. Note examples VIII and IX in US'452 which consequently read on instant claims. Said compounds are made by the instant process as set forth in col.2 and 3 and working example such as 1 of US'452 -the same process described in earlier patent US'513.

Claims 1,2,4-10,19-20,22-28,51-54,56,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivie (US'513 or US'452) and van der Burg (US'848). The teachings of Olivie as discussed in the above rejection are incorporated herein. Compounds in addition to R1 as aryl as taught by Olivie, can be H and such are taught by van der Burg in col.3, 2nd formula as precursors to making mirtazapine. Acyclic precursors are depicted to the right of said compounds and thus preparation of said compounds (as well as R1 as aryl as taught by Olivie) is also suggested by the process taught in Olivie given that the reaction is taught to be simple and straightforward process for making 2- (substituted) phenyl piperazines .

Claims 10-13 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olivie and van der Burg as applied to claims above, and further in view of Winkley.

Winkley is applied as in previous action to show that use of strong bases such as those embraced herein are well known for the same type of ring closure as taught by Olivie who employs pyridine in the working examples.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-36,49,51-53,55-63,65-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,339,156. Although the conflicting claims are no longer identical,

they are not patentably distinct from each other because the narrower scope of process and compound claims in the US patent is embraced by the instant claims which is a continuation of US'156.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600